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Subcutaneous Ocrelizumab in Patients With Multiple Sclerosis: Results of the Phase III OCARINA II Study

Scott D. Newsome * [1],Ewa Krzystanek [2],Krzysztof Selmaj [3],Catarina Figueiredo [4],Christian Wolf [5],Hans-Martin Schneble [4],Oscar Bortolami [4],Heidemarie Kletzl [4],Linda Bursic [4],Dusanka Zecevic [4],Diego Centonze [6, 7],

[1] Johns Hopkins University, Baltimore, United States, [2] Medical University of Silesia, Department of Neurology, School of Health Sciences in Katowice , Katowice, Poland, [3] Centrum Neurologii, Lodz, Poland, [4] F. Hoffman-La Roche Ltd, Basel, Switzerland, [5] Lycalis sprl, Brussels, Belgium, [6] Tor Vergata University, Department of Systems Medicine, Rome, Italy, [7] IRCCS Neuromed, Unit of Neurology, Pozzilli, Italy

Introduction:

Ocrelizumab (OCR) is an effective treatment for people with relapsing and primary progressive multiple sclerosis (RMS/PPMS). The currently available formulation is administered intravenously (IV) every 6 months. A novel OCR subcutaneous (SC) formulation in combination with recombinant human hyaluronidase is being developed.

Objectives/Aims:

OCARINA II (NCT05232825) is a Phase III, randomised, open-label, controlled study designed to demonstrate non-inferiority in serum exposure of OCR when administered via SC versus IV route. This study assesses the pharmacokinetics, pharmacodynamics, safety, tolerability, immunogenicity, radiological and clinical effects of OCR SC versus OCR IV in patients with RMS or PPMS.

Methods:

Patients with RMS or PPMS (18–65 years; Expanded Disability Status Scale [EDSS] score 0.0–6.5) were randomised 1:1 to receive OCR 920 mg SC or OCR 600 mg IV (administered as 300 mg x 2 IV infusions, 2 weeks apart) as first dose (Day 1; baseline [BL]). From Week 24, all patients were scheduled to receive OCR 920 mg SC every 24 weeks up to Week 96. The primary endpoint is the serum OCR area under the concentration-time curve from BL to Week 12 after SC administration compared with IV infusion. Brain MRI, changes in EDSS score, B-cell count, safety, tolerability, immunogenicity and patient satisfaction will also be assessed.

Results:

Two-hundred-and-thirty-six patients across 41 sites were randomized to OCR SC (n=118) and IV (n=118). At BL, mean (standard deviation [SD]) age was 39.9 (11.4)/40.0 (11.9) years, median weight was 75 kg/72 kg and 65.3%/59.3% of patients were female in the SC and IV cohorts, respectively. The majority of participants have RMS (90.7%, 89.8%), the remainder have PPMS (9.3%, 10.2%). The mean (SD) duration since MS symptom onset was 7.7 (8.3) and 6.8 (7.1) years, and mean (SD) duration since MS diagnosis was 5.7 (6.8) and 4.8 (5.8) years in patients receiving OCR SC and IV, respectively. At BL, the mean (SD) number of gadolinium-enhancing T1 lesions was 0.5 (1.7) in OCR SC and 1.0 (2.5) in OCR IV-treated patients. Primary pharmacokinetic results and additional clinical and radiological outcomes from the first 12 weeks of OCARINA II will be presented.

Conclusion:

The BL data of patients enrolled in OCARINA II reflect a typical MS population for which ocrelizumab IV is currently indicated. The new route of administration has the potential to deliver the clinical benefits of ocrelizumab while providing treatment flexibility along with an additional treatment choice.

Disclosures:

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